

What is claimed is:

1. A method of qualifying breast cancer in a subject comprising:
  - (a) measuring at least one biomarker in a sample from a subject, and
  - (b) correlating the measurement with breast cancer status,wherein the biomarker is selected from the group consisting of:
  - Marker I (BC1)
  - Marker II (BC2)
  - Marker III (BC3)
  - Marker IV
  - Marker V
  - Marker VI
  - Marker VII
  - Marker VIII
  - Marker IX
  - Marker X
  - Marker XI
  - Marker XII
  - Marker XIII
  - Marker XIV,
  - and combinations thereof.
2. The method of claim 1 further comprising:
  - (c) managing subject treatment based on the status.
3. The method of claim 2 wherein managing subject treatment is selected from ordering more rests, performing surgery, and taking no further action.
4. The method of claim 2 further comprising:
  - (d) measuring the at least one biomarker after subject management.

5. The method of claim 1 wherein the breast cancer status is selected from the group consisting of the subject's risk of cancer, the presence or absence of disease, the stage of disease, and the effectiveness of treatment.
6. The method of claim 1 wherein measuring comprises detecting by mass spectrometry.
7. The method of claim 1 wherein at least one biomarker is selected from Marker I (BC1), Marker II (BC2), and Marker III (BC3).
8. The method of claim 1 further comprising measuring a known breast cancer biomarker in a sample from the subject and correlating measurement of the known biomarker and the measurement of any one or more of Markers I through XIV with breast cancer status.
9. The method of claim 8 wherein the known biomarker is selected from CA 15.3 or CA 27.29.
10. The method of claim 1 comprising measuring Marker I (BC1), Marker II (BC2), and Marker III (BC3).
11. The method of claim 10 further comprising measuring a known breast cancer biomarker in a sample from the subject and correlating measurement of the known biomarker and the measurement of any one or more of Markers I through XIV with breast cancer status.
12. The method of claim 11 wherein the known biomarker is selected from CA 15.3 or CA 27.29.
13. The method of claim 1 wherein measuring comprises:
  - (a) providing a subject sample of blood or a blood derivative;

(b) capturing one or more of Markers I through XIV from the sample on a surface of a substrate comprising capture reagents that bind the protein biomarkers.

14. The method of claim 13 wherein the substrate is a SELDI probe comprising an IMAC Ni surface and wherein the protein biomarkers are detected by SELDI.

15. The method of claim 13 wherein the substrate is a SELDI probe comprising biospecific affinity reagents that bind one or more of Markers I through XIV and wherein the protein biomarkers are detected by SELDI.

16. The method of claim 13 wherein the substrate is a microtiter plate comprising biospecific affinity reagents that bind one or more of Markers I through XV and the protein biomarkers are detected by immunoassay.

17. The method of claim 1 wherein measuring is selected from detecting the presence or absence of the biomarkers(s), quantifying the amount of marker(s), and qualifying the type of biomarker.

18. The method of claim 1 wherein at least one biomarker is measured using a biochip array.

19. The method of claim 18 wherein the biochip array is a protein chip array.

20. The method of claim 18 wherein the biochip array is a nucleic acid array.

21. The method of claim 18 wherein at least one biomarker is immobilized on the biochip array.

22. The method of claim 1 wherein the protein biomarkers are measured by SELDI.

23. The method of claim 1 wherein the protein biomarkers are measured by immunoassay.
24. The method of claim 1 wherein the correlating is performed by a software classification algorithm.
25. The method of claim 1 wherein the sample is selected from blood, serum and plasma.
26. A method comprising:  
(a) measuring a plurality of biomarkers in a sample from the subject, wherein the plurality of biomarkers is selected from the group consisting of:  
Marker I (BC1)  
Marker II (BC2)  
Marker III (BC3)  
Marker IV  
Marker V  
Marker VI  
Marker VII  
Marker VIII  
Marker IX  
Marker X  
Marker XI  
Marker XII  
Marker XIII, and  
Marker XIV.
27. The method of claim 26 wherein the plurality includes Marker I (BC1), Marker II (BC2), and Marker III (BC3).
28. The method of claim 26 further comprising measuring a known biomarker.

29. The method of claim 26 wherein the known biomarker is selected from CA 15.3 or CA 27.29.

30. The method of claim 26 wherein the protein biomarkers are detected by SELDI or immunoassay.

31. The method of claim 26 wherein the sample is selected from blood, serum and plasma.

32. A method comprising:  
(a) measuring at least one biomarker in a sample from a subject, wherein the biomarker is selected from the group consisting of:

Marker I (BC1)

Marker II (BC2)

Marker III (BC3)

Marker IV

Marker V

Marker VI

Marker VII

Marker VIII

Marker IX

Marker X

Marker XI

Marker XII

Marker XIII, and

Marker XIV,

and combinations thereof.

33. The method of claim 32 further comprising measuring a known biomarker.

34. The method of claim 33 wherein the known biomarker is selected from CA 15.3 or CA 27.29.

35. The method of claim 32 wherein the protein biomarkers are detected by SELDI or immunoassay.

36. The method of claim 32 wherein the sample is selected from blood, serum and plasma.

37. A kit comprising:

(a) a capture reagent that binds a biomarker selected from the group consisting of:

Marker I (BC1)

Marker II (BC2)

Marker III (BC3)

Marker IV

Marker V

Marker VI

Marker VII

Marker VIII

Marker IX

Marker X

Marker XI

Marker XII

Marker XIII, and

Marker XIV,

and combinations thereof; and

(b) a container comprising at least one of the biomarkers.

38. The kit of claim 37 wherein the capture reagent binds a plurality of the biomarkers.

39. The kit of claim 37 wherein the capture reagent is a SELDI probe.
40. The kit of claim 37 further comprising a capture reagent that binds CA 15.3 or CA 27.29.
41. The kit of claim 37 further comprising a second capture reagent that binds one of the biomarkers that the first capture reagent does not bind.
42. A kit comprising:
- (a) a first capture reagent that binds at least one biomarker selected from the group consisting:
- Marker I (BC1)
  - Marker II (BC2)
  - Marker III (BC3)
  - Marker IV
  - Marker V
  - Marker VI
  - Marker VII
  - Marker VIII
  - Marker IX
  - Marker X
  - Marker XI
  - Marker XII
  - Marker XIII, and
  - Marker XIV; and
- (b) a second capture reagent that binds at least one of the biomarkers that is not bound by the first capture reagent.
43. The kit of claim 42 wherein the at least one capture reagent is an antibody.

44. The kit of claim 42 further comprising an MS probe to which at least one capture reagent is attached or is attachable.

45. The kit of claim 42 wherein the capture reagent is an immobilized metal chelate (IMAC).

46. The kit of claim 42 further comprising a wash solution that selectively allows retention of the bound biomarker to the capture reagent as compared with other biomarkers after washing.

47. A kit comprising:  
(a) a first capture reagent that binds at least one biomarker selected from the group consisting of:

Marker I (BC1)  
Marker II (BC2)  
Marker III (BC3)  
Marker IV  
Marker V  
Marker VI  
Marker VII  
Marker VIII  
Marker IX  
Marker X  
Marker XI  
Marker XII  
Marker XIII, and  
Marker XIV;

(b) instructions for using the capture reagent to detect the biomarker.

48. The kit of claim 47 wherein the capture reagent is an antibody.



49. The kit of claim 47 further comprising an MS probe to which the capture reagent is attached or is attachable.

50. The kit of claim 47 wherein the capture reagent is an immobilized metal chelate (IMAC).

51. The kit of claim 47 further comprising a wash solution that selectively allows retention of the bound biomarker to the capture reagent as compared with other biomarkers after washing.

52. The kit of claim 47 further comprising written instructions for use of the kit for detection of cancer.

53. The kit of claim 52 wherein the instructions provide for contacting a test sample with the capture agent and detecting one or more biomarkers retained by the capture agent.

54. An article manufacture comprising:  
(a) at least one capture reagent that binds to at least two biomarkers selected from the group consisting of:

Marker I (BC1)

Marker II (BC2)

Marker III (BC3)

Marker IV

Marker V

Marker VI

Marker VII

Marker VIII

Marker IX

Marker X

Marker XI

Marker XII  
Marker XIII, and  
Marker XIV.

55. The article of manufacture of claim 54 further comprising a capture reagent that binds to a known biomarker.

56. The article of manufacture of claim 55 wherein the known biomarker is CA 15.3 or CA 27.29.

57. A system comprising:  
(a) a plurality of capture reagents each of which has bound to it a different biomarker selected from the group consisting of:

Marker I (BC1)  
Marker II (BC2)  
Marker III (BC3)  
Marker IV  
Marker V  
Marker VI  
Marker VII  
Marker VIII  
Marker IX  
Marker X  
Marker XI  
Marker XII  
Marker XIII, and  
Marker XIV.